SUMMARY OF THE QUALITY SYSTEMS COMMITTEE MEETING MARCH 30, 1999

The Quality Systems (QS) Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met by teleconference on March 30, 1999, at 2 p.m. Eastern Standard Time (EST). The meeting was led by its chair, Mr. Joe Slayton of the U.S. Environmental Protection Agency's (EPA) Region III. A list of action items is given in Attachment A. A list of participants is given in Attachment B. A list of parking lot issues and frequently asked questions is given in Attachment C. Attachment D presents the QS Committee approach to handling comments, comment acknowledgment form letter, commenter template, and guiding principles for reviewing comments and the standard. Attachment E presents the QS Committee responses to comments discussed during this teleconference. Changes to the language in Chapter 5 proposed at this teleconference are reflected in version 5.10.4 of the standard. *The purpose of the meeting was to: review action items from previous meetings, discuss comments received at the NELAC IVi meeting, and discuss comments received since NELAC IVi.*

REVIEW OF ACTION ITEMS FROM THE PREVIOUS MEETING

The committee reviewed the action items from the previous meeting, which was held by teleconference on March 16, 1999. Items not already completed or addressed at today's meeting will be carried over to the next meeting.

DISCUSSION OF ISSUES RAISED AT NELAC IVI

Section 5.9.4.2.2.b: The language was modified at the previous meeting to allow only one continuing calibration check (at the beginning of each analytical batch) if the analytical instrument uses internal standards.

Section 5.9.4.2.2.c: The committee discussed how to make this item consistent with the previous changes made to item b above. If, in addition to an internal standard, only one continuing calibration verification is required, at what concentration level should this be evaluated? The points raised during this discussion were:

- the best concentration level to run this calibration verification will depend upon the use of the data,
- the best approach may be to default to the requirements of the analytical method being used and not specifying concentration levels in the standard,
- two calibration verification points should be evaluated in order to properly characterize the response line, and
- a possible option would be to allow a calibration verification at the midpoint of the calibration ranges, which is commonly done with analytical instruments using internal standards.

The committee decided to take a less prescriptive approach and revised the language in Section 5.9.4.2.2.b and deleted Section 5.9.4.2.2.c. The revised language in Section 5.9.4.2.2.b would read as follows:

> *b) A continuing instrument calibration verification must be repeated at the beginning and end of each analytical batch. The concentrations of the calibration verification shall be varied within the established calibration range. If an internal standard is used, only one continuing instrument calibration verification must be analyzed per analytical batch.*

Section 5.9.4.2.2.f.i and ii: The discussion on this section pertained to a comment received from Mr. Larry Jackson. The committee decided against making the suggested revisions to the standard. See Attachment E for Mr. Porterfield's response to Mr. Jackson's comment on this section. The committee will address Mr. Jackson's comments on other sections of Chapter 5 as they review the corresponding sections. These comments and responses will be presented in the minutes of the meeting at which they are discussed.

Section 5.9.4.2.2.f.ii: The discussion on this section pertains to a comment received from Mr. Jack Hall of Quanterra. Mr. Porterfield's response is given in Attachment E. Quanterra's submittal also included comments on other sections of Chapter 5 which will be addressed when the corresponding sections of Chapter 5 are reviewed. These comments and responses will be presented in the minutes of the meeting at which they are discussed. The committee decided to amend the language in this section as shown below.

> *ii. When the acceptance criteria for the continuing calibration verification are exceeded low, i.e., low bias, those sample results may be reported if they exceed a maximum regulatory limit/decision level. Otherwise the samples affected by the unacceptable verification shall be reanalyzed after a new calibration curve has been established, evaluated and accepted.*

Work Cells

Section 5.6.2 (Note): The committee discussed how the demonstration of initial capability should be applied when laboratory personnel are organized into "work cells." The issue was how to demonstrate initial capability as personnel move in and out of the work cell group. The discussion points were:

- the requirement should not be that the entire work cell must demonstrate initial capability each time new personnel are added to a work cell, and
- ongoing quality control checks, such as continuing calibration verification or laboratory control samples, may be adequate for ensuring that a work cell (with a new member) is properly performing the phase of analysis for which it is responsible.

The QS Committee decided to take a less prescriptive approach and modify the language in the note as shown below. In addition, the note was moved to after Section 5.6.2.b because it applies more directly to this section.

> *Note: In laboratories with specialized "work cells" (defined as a group of analysts that together perform the method analysis), the group as a unit must meet the above criteria and this demonstration fully documented.*

Initial Demonstration of Capability (IDOC)

Section C.1: A question was raised about laboratories that may have already been doing analyses of real world samples but have not performed an initial demonstration of method performance in an applicable and available clean (blank) matrix. The question is, can these laboratories use the real world data they have already generated in lieu of data from analyses in a clean (blank) matrix? Language was added to the introductory paragraph of Section C.1 as shown below in the double underlined text.

> *This section does not test performance in real world samples, but in the applicable and available clean matrix (a sample of a matrix in which no target analytes or interferences are present at concentrations that impact the results of a specific test method), e.g., water, solids, biological tissue, and air. However, for newly accredited laboratories, actual sample spike results may be used to meet this standard, i.e., historical data not to exceed the last immediate 12 months.*

Similar language was added to Section 5.10.2.1.a, which is referenced in Section C.1, for consistency.

Section C.1: The procedure adapted from 40 CFR Part 136 was changed from a requirement to an example of how to perform the initial demonstration of capability. The language was modified as follows.

> *The following steps, which are adapted from the EPA test methods published in 40 CFR Part 136, Appendix A, ~~shall be performed~~: are one way to perform this initial demonstration. It is the responsibility of the laboratory to document that other approaches to IDOC are adequate and this shall be documented in the laboratory's Quality Assurance Manual.*

Appendix C, Certification Statement: *Method* was changed to *method/s* in items 1, 2, and 3 so that more than one method could be addressed per certificate.

COMMENTS RECEIVED

The QS Committee's policy on accepting comments is that they must be submitted in the table format provided in Attachment D. In addition, the comments must be submitted as WordPerfect (with the wpd extension), Rich Text Format (with the rtf extension), or MS Word (with the doc

extension) files. Furthermore, the commenters should use a simple and uniform font throughout the comment.

New Hampshire: The committee reviewed Mr. Slayton's response to the comments received from New Hampshire. Attachment E that contains the response.

Oregon: The committee reviewed Mr. Slayton's response to the comments received from Oregon. Attachment E that contains the response.

New Jersey: The committee reviewed Mr Slayton's and Mr. Siegelman's responses to the comments from the New Jersey Department of Environmental Protection. The responses and comments are included in Attachment E. Mr. Siegelman's response added the requirement of recording the time of the analysis in addition to the date. Mr. Slayton's response involved adding item f to Section D.3.8, which is presented below.

f) UV Sterilizers

1) Are to be tested quarterly for effectiveness with positives (either reference cultures or positive monitoring samples) and this is to include testing of the power output of the UV bulb.

Attachment A

ACTION ITEMS
QUALITY SYSTEMS COMMITTEE
MARCH 30, 1999

Item No.	Action Item	Date to be Completed
1.	Joe Slayton to send Mike Cross E-mail distribution list for QS Committee	
2.	Chuck Glowacki to lead a discussion, at the April 6, 1999 meeting (teleconference), concerning the comments and revisions to the air testing section of Chapter 5. He will distribute a draft of the revised section prior to the next meeting.	
3.	Raymond Frederici will provide an example form to address the requirements of the IDOC Capability Certification Statement	
4.	Mr. Slayton will add the new requirements and suggestions for how to submit comments to the QS Committee to the procedure for handling comments.	
5.	Mr. Slayton will update the new table for tracking comments submitted to the QS Committee.	
6.	Donivan Porterfield to provide language addressing initial demonstration of capability for analytical methods for which spiking is not applicable.	
7.	The next meeting (by teleconference) is April 6th from 1 p.m. to 4 p.m. Eastern Daylight Time (EDT) on 202-260-8330, access number 8983#. The agenda includes review of comments from Quanterra, Dow, Mr. Larry Jackson, Severn Trent Laboratory, and ELAB. QS Committee responses to these comments should be completed for this meeting.	

Attachment B

PARTICIPANTS
QUALITY SYSTEMS COMMITTEE
MARCH 30, 1999

Name	Affiliation	Phone/Fax/E-mail
Slayton, Joseph Chair	U.S. EPA/Region 3	T: 410-305-2653 F: 410-305-2698 E: slayton.joe@epamail.epa.gov
Bruch, Mary	Mary Bruch Micro Reg. Inc.	T: 703-589-1514 F: 703-779-0267 E: --- none ---
Frederici, Raymond	Recra Labnet	T: 708-534-5200 F: 708-534-5211 E: frederir@recra.com
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Mendenhall, David	Utah Dept of Health	T: 801-584-8470 F: 801-584-8501 E: dmendenh@doh.state.ut.us
Meyers, Sheila	TNRCC	T: 512-239-0425 F: 512-239-6307 E: smeyers@.tnrcc.state.tx.us
Nielsen, Jeffrey	City of Tallahassee, Water Quality Division	T: 850-891-1232 F: 850-891-1062 E: nielsenj@mail.ci.tlh.fl.us
Porterfield, Donivan	Los Alamos National Lab., AQ & CIM	T: 505-667-4710 F: 505-665-4737 E: dporterfield@lanl.gov
Siders, Scott (Absent)	Illinois EPA	T: 217-785-5163 F: 217-524-0944 E: epa6113@epa.state.il.us
Siegelman, Fred	USEPA/ORD/QAD	T: 202-564-5173 F: 202-565-2441 E: siegelman.frederic@epamail.epa.gov
Cross, Mike (Contractor Support)	Research Triangle Inst.	T: 202-728-2045 F: 202-728-2095 E: myc@rti.org

Attachment C

PARKING LOT ITEMS/ISSUES AND
FREQUENTLY ASKED QUESTIONS
QUALITY SYSTEMS COMMITTEE
MARCH 30, 1999

Items/issues will remain in the Parking Lot until they are completed.

1. Air Appendix

Need to review and finalize

2. Initial Demonstration of Capability (IDOC)

Need to address an IDOC for tests for which you cannot spike. Also, does IDOC need to be universal and address all medias? Donivan Porterfield is lead.

3. Definitions/Glossary

Changes necessary to be consistent with Program Policy and Structure proposal. QS Committee will review definitions/glossary at interim meeting.

4. Review comments received since NELAC IVi.

5. Need to vote in two new members to QS Committee.

All candidates must be identified and voted upon by NELAC committees by May 10, 1999. All appointments by the NELAC chair must be complete by May 17, 1999.

6. Final QS Chapter for NELAC V

Final changes to standards are due to Research Triangle Institute by April 29, 1999 for posting on the NELAC Website prior to the annual meeting. This version will be posted within a week and half of receipt and will remain as the final proposed text for Annual Meeting.

7. Agenda for NELAC V

Final committee agendas, including discussion items and times, are due to Elizabeth Dutrow by May 10, 1999.

Some Frequently Asked Questions Concerning NELAC QS (Chapter 5):

1. Question: If a mandated method (required by EPA or State Authority) is less stringent than the QS standards, what do I follow?

Answer: The most restrictive/demanding.

2. Question: Do the QS standards require the use of any specific method?

Answer: No

3. Question: Do the QS standards allow for the use of the performance-based measurement systems (PBMS) approach?

Answer: Yes. However, the QS standards may include additional QS checks/requirements (considered by NELAC to be essential) than those associated with a PBMS method for a given project. Such additional requirements would also apply to conventional or non-PBMS methods as well.

4. Question: Do the QS standards apply to small laboratories?

Answer: Yes. The standards include essential QC procedures and are applicable to environmental laboratories regardless of size and complexity. It is suggested that the amount of effort that will be required to attain the standards will be dependent on whether the laboratory already is operating under a quality system (with established and documented standard operating procedures (SOPs) and QC procedures) more than upon the size of the laboratory.

5. Question: If my laboratory is measuring high level concentrations and is set-up (perhaps even optimized) to analyze at such levels and is only interested in whether a high level regulatory limit is exceeded, why do I have to determine a detection limit?

Answer: A detection limit is considered essential to verify (confirm and document) that the laboratory is actually able to detect and measure at the regulatory or decision limit. Detection limit determinations are also considered an important consideration with regard to the quantitation range selection and particularly with regard to the choice of the concentration of the lowest calibration standard. Changes to the standard will be proposed at the January 1999 Interim Meeting, which no longer specify that the method detection limit (MDL) (40 CFR Part 136) procedure be employed, unless it is mandated by the test method or applicable regulation. In the proposed revision, the term "detection limit" may not be the lowest concentration level attainable by a given analytical method, but rather that it is a concentration that is actually measurable (and verified) using the procedures, e.g., equipment, analytical method, routinely employed for sample analyses (could be relatively high concentration). The detection level should be appropriate or relevant for the intended use of the data. In some cases this will of necessity be the lowest concentration level attainable, e.g., low level drinking water or wastewater permit limits.

6. Question: Why are we revisiting the calibration and detection parts of the standards?

Answer: At NELAC IV the Quality Systems Committee received numerous comments that the calibration and detection parts of the standards were too prescriptive and were not consistent with a PBMS environment. The committee has attempted to propose changes to the calibration and detection parts of the standards that provide essential elements for those two quality system standards and that will support the anticipated needs of PBMS. The committee believes the proposed language is less prescriptive (i.e., more flexibility), yet hopefully still ensures the quality of the analytical data.

In making these proposed changes the committee has attempted to balance the need for more flexibility in the standards with the desire to not go too far and introduce excessive flexibility that could prove to be too vague or ill-advised. The committee is currently discussing and considering its proposed language and public comments on the proposed language changes. The committee is committed to assuring that the NELAC Quality Systems standards provide a foundation for PBMS implementation.

7. Question: Several States have indicated that it is very desirable that a laboratory already be actively analyzing samples for a particular program and by a method for which they want to be accredited. However, these same states have relayed that this ideal scenario is often not the case, as a laboratory may request accreditation in attempts to expand their scope of analytical services or in order to satisfy contractual requirements. These states ask: How will the QS standards help ensure that laboratories will have sufficient data for an onsite assessment, especially given the proposed changes to the MDL section?

Answer: The MDL, Section D.1.4, in the 1998 NELAC standards has a requirement that "MDLs" be determined initially (40 CFR Part 136, Appendix B) and be verified yearly by the analysis of at least one clean matrix sample spiked at the current reported MDL. Under the proposed revision to Section D.1.4, "Detection Limits" are to be determined initially and each time there is significant change in the test method or instrument type. The proposed standard still requires "MDL" if required in the mandated test method or applicable regulation. If the MDL is not required a "detection limit" must still be determined. Therefore the new Section D.1.4 requirements should still help assure that performance data will be available for review by inspectors . In addition, laboratories are required to successfully complete two out of three proficiency testing (PT) samples yearly and this data would be available for review, as per section 5.5.4 and Chapter 2) . However, under the current PT requirements this may only include one method of multiple methods employed by a laboratory for a given parameter group, e.g., metals.

Laboratories also must perform an IDOC (5.10.2.1, D.1.3 Method Evaluation and Appendix C) . This data would be available for on-site review. Also note that the QS committee plans to expand Appendix C (IDC) procedures prior to NELAC V to make it applicable to methods for which spiking is difficult or impossible, e.g., Total Suspended Solids, which should further ensure that performance data is available for review.

In addition, under Section 5.6.2.3.c. of QS, the Laboratory Management must ensure that the training of personnel is kept up-to-date, which includes a analyst certification to perform the most

recent version of the test method (the approved method or standard operating procedure) and documentation of continued proficiency by at least one of the following once per year:

i: acceptable performance of a blind sample (single blind to the analyst),

ii: another initial demonstration of method capability,

iii: successful analysis of a blind performance sample on a similar test method using the same technology,

iv: at least four consecutive laboratory control samples with acceptable levels of precision and accuracy, and

v: if i-iv cannot be performed, analysis of authentic samples that have been analyzed by another trained analyst with statistically indistinguishable.

These requirements should further help assure performance data is available on-site for review.

Attachment D

ACKNOWLEDGEMENT LETTER, REVIEW GUIDELINES, AND COMMENTER TEMPLATE
QUALITY SYSTEMS COMMITTEE
MARCH 30, 1999

Date:

Dear :

On behalf of the Quality Systems Committee, thank you for your comments on the Chapter 5 standards of the National Environmental Laboratory Accreditation Conference (NELAC). The standards are routinely reviewed and updated. Continual improvement of the standards is the focal point of NELAC process. We encourage your continued written input as well as your attendance at the NELAC interim meeting and yearly conference. Also, our committee routinely schedules 1-2 open forum meetings during each calender year.

Our committee requests that all comments be supplied in electronic format (WordPerfect if possible) and that handwritten, hardcopy and the use of color fonts be avoided. Comments are considered by the QS committee on a first come basis. We have placed a template (table) for comments on the NELAC Web page, which we hope will ensure that the processes is efficient. With this process we hope that emphasis can be placed on consideration of the comments so that the available time is not spent in the mechanics of exchanging information (US Mail and re-typing comments). Routinely, each set of comments is assigned a QS leader who will complete the comment table including suggested language for any proposed changes to the NELAC standards. The Leader will guide a discussion of the comments during routine committee meetings. The minutes of the meeting (posted on the web site) will capture the information in the completed table from committee discussions, thoughts/rationale and present the final decisions.

Again, thank you for taking the time and effort to improve the NELAC Quality System standards.

Sincerely,

Joseph Slayton, Chair
Quality Systems Committee

QS Approach: **Comments Received and QS Response:**

1. A form letter will be sent to each commentor notifying them of receipt of the comment and of the QS's approach to reviewing comments and associated updates to the standards.

2. QS will consider the comments in the order received.

3. A QS committee member will be designated as the lead on each set (or up-set) of the comments from each commentor, who will provide written comments and who will lead a discussion with the full committee on any proposed changes to the standards (including providing the proposed standard language).

4. Proposed changes to the standards will be captured in the QS meeting minutes which are posted on the NELAC Web page.

5. All comments and written responses will be attached to QS meeting minutes.

6. No colors to be used in the comments nor in the response. Use double underlines for additions and strike-outs for removal of items.

7. All comments are to be provided in WordPerfect or rich text format using the following the following table:

GUIDING PRINCIPLES/REVIEW CRITERIA

The QS Committee established a set of criteria by which to evaluate the requirements specified in Chapter 5. The standards in Chapter 5 should meet the criteria listed below:

Flexible:

Allow laboratories freedom to use their experience and expertise in performing their work and allow for new and novel analytical methods and approaches, (e.g., Performance Based Measurement System [PBMS]). That the standards specify the "What" and avoid were possible the "How To", (e.g., control limits must be developed to determine if a QC check result is acceptable, the standards do not specify how the laboratory is to determine these limits).

Auditable:

Sufficient detail is included so that the accrediting authorities evaluate laboratories consistently and uniformly.

Practical/Essential:

The standards are necessary QA policies and QC procedures and that these standards should not place an unreasonable burden upon laboratories.

Widely Applicable:

International scope- consistent with ISO Guide 25. Represent QA policies, which establish essential QC procedures, that are applicable to environmental laboratories regardless of size and complexity.

Appropriate For The Use of the Data:

Helps ensure that associated environmental data is of known quality and that the quality is adequate for the intended use of the data.

Comment ID #: , Source of Comments (Name): QS Lead on Response (Name):			
Standard Rev. # SECTION# and QS Standard Narrative (To Filled In by Commentor)	**COMMENTwith Rationale to QS (To Be Filled in my Commentor)** **New Wording for Standard (To Be Filled In by Commentor)**	**QS Leader Provided Proposed Change (Commentor Leave Blank)**	**RATIONAL (from QS Leader) (Commentor Leave Blank)**

Attachment E

QS COMMITTEE RESPONSES TO COMMENTS
Quality Systems Committee
March 30, 1999

Source of Comments (Name): NJ DEP (Michele Kropilak & Dr. Michael Miller) **QS Lead on Response (Name):** Fred Siegelman			
Standard Rev. # SECTION# and QS Standard Narrative (To Filled In by Commentor)	**COMMENTwith Rationale to QS (To Be Filled in by Commentor) New Wording for Standard (To Be Filled In by Commentor)**	**QS Leader Provided Proposed Change (Commentor Leave Blank)**	**RATIONAL (from QS Leader) (Commentor Leave Blank)**
5.9.4.2 Instrument Calibrations	Suggestion: Insert a paragraph – The laboratory must have a written policy on the determination of the concentration of an analyte which includes: 1) Determination of the baseline 2) Integration of chromatographic peak area 3) Integration of spectrophotometric peak area and 4) Determination of peak height.	No change.	Proposed text is for chromatographic analysis and instrumentation only. 5.9.4.2 must be appropriate for any type of instrument calibration. The intention of 5.9.4.2 is "This standard does not specify detailed procedural steps ("how to") for calibration, but establishes the essential elements for selection of the appropriate technique(s)". For chromatographic analysis, these items would be in the SOP referenced in 5.9.4.2.1 (a) and 5.9.4.2.2 (a)

Source of Comments (Name): NJ DEP (Michele Kropilak & Dr. Michael Miller) **QS Lead on Response (Name):** Fred Siegelman			
5.12.3.3 Analytical Records	Suggestion: Add g) – Time of analysis (for those samples with short holding times)	Change "**5.12.3.3 Analytical Records** b) Date of analysis;" to "**5.12.3.3 Analytical Records** b) Date and time of analysis;"	Suggestion is valid and is required by what Standard now requires for laboratory report: "5.13 (a) (7) date of receipt of sample, date and time of sample collection, date(s) of performance test, and time of sample preparation and/or analysis if the required holding time for either activity is less than or equal to 48 hours;" Changing 5.12.3.3 (b) to date and time is consistent with the current text in a number of places and is simpler than adding a 5.12.3.3 g)
5.13 Laboratory Report Format and Contents	Suggestion: in (e) change "promptly" to within 3 calendar days.	No change	This text is identical with the text in ISO 25 13.6. In addition, the change would require defining the start of the time period since "within 3 calendar days" could be subject to different interpretations.

Source of Comments (Name): NJ DEP (Michele Kropilak & Dr. Michael Miller) **QS Lead on Response (Name):** Joe Slayton			
Appendix D D.1.1b 1&2	Suggestion: Change frequency of one per 20 samples to :one per 20 samples or once per month if less thqn 20 samples analyzed per month. This would cove the small labs who might only analyze one sample a month for compliance.	No Change	It is agreed that infrequent analyses places a greater % of analytical time on QC, i.e., the smaller the actual sample batch the greater the percentage of the work will be spent performing the required QC. However, in terms of the user of the data, infrequent monitoring and analysis means that important compliance decisions are being made on very little data which is consistent with the increased proportion of time being spent on the associated QC analyses.

Source of Comments (Name): NJ DEP (Michele Kropilak & Dr. Michael Miller) **QS Lead on Response (Name):** Joe Slayton			
D.3 Microbiology	Some QC required by EPA Lab Cert manual 4th edition are not included in QS, including: 1) checking sterility of buffer water used; 2) checking sterility of sample bottles before use; 3) UV sterilizers-testing sterilizers quarterly for effectiveness	Items 1) and 2): Suggest D.3.1.a (opening paragraph), be reworded to include these items 3) Suggest add section D.3.8.f UV Sterilizers. Requires the check of the UV sterilizer.	1 & 2) Additional clarification. 3) Addition to standard.
D.3 Microbiology	Positive Controls: The requirements for those labs which use pre-prepared media of analyzing a positive with each batch of samples seems excessive. As long as lab monitoring expiration dates and running positive on each lot or perhaps monthly, that should be sufficient	No Change	We think that this was addressed in the proposed language change to D.3.1.b.

March 29, 1999

RaeAnn Haynes, QA Manager
State of Oregon

Dear Ms. Haynes:

On behalf of the NELAC QS Committee, thank you for your comments. We request that future comments and suggests be submitted to the QS Committee by completing the table format which is attached to our Committee minutes on the NELAC Web page.

Your comments concerned Method Detection Limits (MDLs) and indicate the importance of this determination to laboratory assessors in helping to establish that a laboratory is capable and ready for an on-site inspection/audit. The proposed language change to D.1.4 Detection Limits, still requires the determination of detection limits and if MDLs are required by mandated method or applicable regulations MDLs would have to be determined. Whether an MDL or another detection measure/statistic is appropriate under regulation/method, such determinations would be required initially, prior to processing samples and any time a significant change in test method or instrument type. This is also the same for QS's IDOC (the latter also mentioned in your comment directed to Chapter 5). We feel this approach will afford flexibility yet provide the needed safeguards to assure data of known quality appropriate for its intended use and should still help assessors determine if a laboratory is ready for an on-site assessment.

Sincerely,

Joseph Slayton, Chair
QS Committee

March 29, 1999

Charles Dyer
Program Manager
State of New Hampshire
Department of Environmental Services
6 Hazen Drive
P.O. Box 95
Concord, NH 03302-0095

Dear Mr. Dyer:

On behalf of the QS committee I would like to thank you for your letter and the comments from Russell D. Foster, Technical Director, RLI Resource Laboratories, Inc and from SCITEST Laboratory Services (Joann). We request that in future submissions that you employ the comments template that QS's has routinely included with our meeting minutes on the NELAC Web page.

1. Definition of Preparation Batch, appendix B, page 5B-1. The QS committee agreed upon 20 samples per batch as being consistent with EPA and good laboratory practices. The batch size, drives the analysis of additional QC samples, e.g., method blank and laboratory control samples. In addition, we too wrestled with the need for a time limit in this criteria. The consensus reached: "...with a maximum time between the start of processing of the first and last sample in the batch to be 24 hours". The stress here is "start of process" and we realize that as manufactures provide various automated (sequential) devices this may be problematic, however additional QC under such an automated scenario should have decreased impact on laboratory throughput.

2 Request for clarification of the NELAC standard regarding labeling sample containers (NELAC 5.11.1.a). The letter from the Vermont laboratory indicates "...each of the four (sample) bottles has a distinct label, with two distinct Work Order #3". NELAC (5.11.1.a) requires that: "The laboratory shall assign a unique identification (ID) code to each sample container received in the laboratory. The use of container shape, size or other physical characteristic, such as amber glass, or purple top, is not an acceptable means to identifying the sample". The "distinct label" you have indicated should meet the "unique sample (ID) code" requirement, as long as, " This laboratory code shall maintain an unequivocal link with the unique field ID code assigned each container (5.11.1.b) and "The laboratory ID code shall be entered into the laboratory records and shall be the link that associates the sample with related laboratory activities such as sample preparation or calibration " (5.11.1.d).

Sincerely,

Joseph Slayton, Chair
QS Committee

Review comments on NELAC Quality System Std., rev 10.1 dated 1/13/99

Commentor: Larry P. Jackson, e-mail to lpjackson@MSN.com, tel. 603/924-6852
QS Response: Donivan Porterfield

Comment #	Section #	Current Text	Suggested Revision And Rational	QS Leader Proposed Change	Rational for Change
10	5.9.4.2.2 f) i. and ii.		Sections 5.9.4.2.2 f) i. and ii. of rev 10.1 have become confusing as they attempt to provide clarification. If the continuing calibration verification (CCV) sample is out of control in either direction, the client samples should be reanalyzed after appropriate corrective action. The existing text in f) is clear on this point and should be retained. If it is necessary to report the client sample data without reanalysis e.g. lack of sufficient sample, there should be no differentiation of the impact of high or low bias in the CCV based on the observed client sample values. It makes no difference if the samples were non-detects, detected but below a regulatory limit/decision level, or detected above a regulatory limit/decision level because ALL the results may be biased based on the CCV performance. The laboratory has a responsibility to reports the facts related to data quality. The client has the responsibility to determine the impact on data utilization. As written, Sections i. and ii. have implicitly intruded into the area of assessment of the impact of the CCV on data quality by specifying what sample data can be reported as a function of direction of the CCV bias, detect/non-detect observations and regulatory limit/decision level. If any data is reported from the analytical batch, then all data must be reported. Appropriate qualifiers must be attached to all data. The client can than interpret the impact on usability. **Suggested Resolution:** Delete the last sentence of section f) and all of sections i. and ii. Replace the deleted text with the following paragraph: *Sample data obtained after successful corrective action and reanalysis shall be reported with no flags related to CCV performance. If sufficient sample was not available for reanalysis of some samples after recalibration, the original sample data associated with the unacceptable CCV shall be flagged and reported with appropriate discussion in the case narrative. As part of the discussion, in the case narrative, all data obtained on samples from the original batch that were reanalyzed shall be included. This will allow the data user to assess any impact on data quality arising from the failed CCV by comparing the before and after results on samples from the same analytical batch.*		Given the time spent in the initial discussion of this section I'm hesitant to make the suggested change. However, I would note that this change continues to allow the acquired data to be reported - it simply does make any judgements on the data to be reported based on the possible direction of the bias. The basic question is whether the 'penalty' of reporting flagged data will assure that the laboratory will take the necessary steps to avoid generation of such data in the first place. I would note a problem with the suggested text. It seems to propose that where reanalysis is not possible, i.e. insufficient sample, that it was indeed possible to generate "before and after results". This scenario seems incongruous with the circumstances presented.

Comments from: Jack Hall, Quanterra
QS Review: Donivan Porterfield, LANL

Standard Rev. #, Section # and QS Standard Narrative (To Be Filled In by Commentor)	Comment to QS (To Be Filled In by Commentor)	QS Leader Provided Proposed Change (Commentor Leave Blank)	Rational (From QS Leader) (Commentor Leave Blank)
ALL below are on Rev 9			
5.9.4.2.2 item f ii When the acceptance criteria for the continuing calibration verification are exceeded low, i.e., low bias, these sample results may be reported if there are associated samples that exceed a maximum regulatory limit/decision level.	Need to clarify does it really allow all samples to be reported if biased low and only a few samples are above the action / regulatory level???	When the acceptance criteria for the continuing calibration verification are exceeded low, i.e., low bias, those ~~these~~ sample results may be reported ~~if there are associated samples~~ that exceed a maximum regulatory limit/decision level.	I believe that the proposed change is more in line with the discussion we had in MD back in November.